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COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Regulation (EC) No 998/2003 on the animal health requirements applicable to
the non-commercial movement of pet animals**

{SEC(2009)776}
{SEC(2009)777}

EXPLANATORY MEMORANDUM

The purpose of this Commission proposal is to amend Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC¹.

This Commission proposal is supported by the Commission staff working document on the impact assessment of the review of Regulation (EC) No 998/2003.

Legal background

In accordance with Regulation (EC) No 998/2003, pet dogs, cats and ferrets travelling with their owner to another Member State must be accompanied by a passport, or when imported by a certificate, providing proof of a valid anti-rabies vaccination ('general regime'). As of 3 July 2011 electronic identification of dogs, cats and ferrets will be mandatory.

In order to take account of the particular situation of Ireland, Malta, Sweden and the United Kingdom ('the UK') with regard to rabies, Regulation (EC) No 998/2003 provides for a transitional period during which the entry of pet dogs and cats into those Member States is subjected to more stringent requirements.

For the same transitional period, Finland, Ireland, Malta, Sweden and the UK are allowed to make the entry of pet animals into their territory subject to additional requirements for the tapeworm echinococcus and ticks.

Initially the transitional period lasted until 3 July 2008. As recommended by the Commission report adopted on 8 October 2007 pursuant to Article 23 of Regulation (EC) No 998/2003, the transitional period was extended to 30 June 2010 by Regulation (EC) No 454/2008 of the European Parliament and of the Council amending Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movements of pet animals, as regards the extension of the transitional period².

The issue

In view of determining the regime to be applied from 1 July 2010 for Articles 6, 8 and 16 of Regulation (EC) No 998/2003, as required by Article 23 of that Regulation, the Commission carried out an impact assessment on the basis of its report, that takes into account various opinions of the European Food Safety Authority (EFSA) on the risk of introducing rabies, echinococcus and ticks into the five Member States if national rules were abandoned, and of various recent consultations of interested parties.

The opinions adopted by EFSA identified that certain Member States have a non negligible prevalence of rabies in their pet population, which is related to the rabies situation in wildlife. In addition, EFSA recommended that risk mitigating measures should be implemented with respect to movement of pet animals from those Member States.

Rabies in those Member States is primarily of sylvatic nature. Field evidence demonstrated that with the elimination of sylvatic rabies as a result of intensive programmes of oral

¹ OJ L 146, 13.6.2003, p. 1.

² OJ L 145, 4.6.2008, p. 238.

vaccination of wildlife, the disease occurrence in domestic animals diminishes. The Commission has approved a number of programmes for the eradication of rabies in those Member States and envisages ending EU support to national programmes in the territory of those Member States by the end of 2011.

In view of the EFSA opinions and of the Community-supported programmes, the transitional measure provided for in Article 6 of Regulation (EC) No 998/2003 should be extended until 31 December 2011.

Moreover, from the opinions adopted by EFSA with regard to echinococcosis and ticks, it results that the data available did not allow EFSA to demonstrate a particular status of the five Member States applying the transitional regime with regard to certain ticks and the tapeworm *Echinococcus multilocularis* and to quantify the risk of pathogen introduction through the non-commercial movement of pet animals.

For reasons of consistency however, it is appropriate to extend also the transitional measure provided for in Article 16 of Regulation (EC) No 998/2003 until 31 December 2011.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee³,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) Regulation (EC) No 998/2003⁵ lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules applying to checks on such movements.
- (2) Article 5 of that Regulation lays down provisions applicable to movement between Member States of dogs, cats and ferrets as listed in Parts A and B of Annex I thereto. Pursuant to Article 5(1)(a), the animals must be identified by means of an electronic identification system (transponder). For an eight-year transitional period from the entry into force of that Regulation, those pet animals are to be regarded as identified also where they bear a clearly readable tattoo.
- (3) Article 4(1) and Article 14 of Regulation (EC) No 998/2003 provide that, where the transponder does not comply with ISO Standard 11784 or Annex A to ISO Standard 11785, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.
- (4) In order to avoid any unnecessary disturbances, in particular as regards the movements from third countries, it is necessary to make more precise the references to those ISO Standards, before the use of transponders becomes mandatory. Due to the technical

³ OJ C [...], [...], p. [...].

⁴ OJ C 325, 24.12.2002, p. 133.

⁵ OJ L 146, 13.6.2003, p. 1.

nature of those references, it is appropriate to include them in an Annex and amend Articles 4 and 14 accordingly.

- (5) In addition, Article 5(1)(b) of Regulation (EC) No 998/2003 provides that dogs, cats and ferrets must be accompanied by a passport issued by a veterinarian authorised by the competent authority, certifying valid anti-rabies vaccination, in accordance with the recommendations of the manufacturing laboratory, carried out on the animal in question, with an inactivated rabies vaccine of at least one antigenic unit per dose (WHO standard). Since the adoption of Regulation (EC) No 998/2003, recombinant vaccines have also become available for the purposes of anti-rabies vaccination.
- (6) In order to allow the movement of dogs, cats and ferrets vaccinated with recombinant vaccines, in particular from third countries, provision should be made to also authorise, for the purpose of Regulation (EC) No 998/2003, the use of such vaccines in accordance with certain technical requirements laid down in an Annex to that Regulation.
- (7) If administered in a Member State, the vaccines must have been granted a marketing authorisation in accordance with either Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁶ or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁷.
- (8) If administered in a third country, the vaccines should comply with the minimum standards for safety as laid down in the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE).
- (9) In addition, the Commission should be empowered to lay down science based rules of a similar kind as those laid down for rabies and providing for preventive measures for the movement of pet animals regarding other diseases that may affect those animals, where those preventive measures are proportionate to the risk of spreading those diseases due to such movement. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 998/2003, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down procedures for the exercise of implementing powers conferred on the Commission⁸.
- (10) Article 6 of Regulation (EC) No 998/2003 provides that the entry of dogs and cats into Ireland, Malta, Sweden and the United Kingdom is to be subject to additional requirements, in view of the particular situation in those Member States with regard to rabies. That provision is to be applied until 30 June 2010, as a transitional measure.

⁶ OJ L 311, 28.11.2001 p. 1.

⁷ OJ L 136, 30.4.2004, p. 1.

⁸ OJ L 184, 17.7.1999, p. 23.

- (11) According to those additional requirements, those pet animals entering the territory of those Member States must be identified by means of a transponder unless the Member State of destination also recognises that the animal may be identified by means of a clearly readable tattoo. In addition, those requirements include the mandatory antibody titration before entry of the pet animals into the territory of those Member States, to confirm a protective level of anti-rabies antibodies.
- (12) Article 8 of Regulation (EC) No 998/2003 lays down the conditions for the movement of dogs, cats and ferrets from third countries depending on the prevailing rabies situation in the third country of origin and in the Member State of destination.
- (13) Article 8(1)(a)(ii) of Regulation (EC) No 998/2003 provides that, in cases where pet animals are moved from certain third countries to Ireland, Malta, Sweden and the United Kingdom, the additional requirements provided for in Article 6 are to apply. Those third countries are listed in Section 2 of Part B and in Part C of Annex II to Regulation (EC) No 998/2003.
- (14) Article 8(1)(b)(ii) of Regulation (EC) No 998/2003 provides that, in cases where pet animals are moved from other third countries, they are to be placed in quarantine unless they have been brought into conformity with the requirements of Article 6 of that Regulation after their entry into the Community.
- (15) In addition, Article 16 of Regulation (EC) No 998/2003 provides that Finland, Ireland, Malta, Sweden and the United Kingdom as regards echinococcosis, and Ireland, Malta and the United Kingdom as regards ticks, may make the entry of pet animals into their territory subject to compliance with the special rules in place on the date on which that Regulation came into force. That provision is to be applied until 30 June 2010, as a transitional measure.
- (16) Article 23 of Regulation (EC) No 998/2003 provides that the Commission, after receipt of the opinion of the European Food Safety Authority (EFSA) on the need to maintain the serological test, and based on experience gained and on a risk evaluation, is to submit to the European Parliament and to the Council a report, together with appropriate proposals for determining the regime to be applied with effect from 1 July 2010 for Articles 6, 8 and 16 of that Regulation.
- (17) In order to determine that regime, the Commission carried out an impact assessment based on various recent consultations and on the report that was adopted on 8 October 2007⁹ pursuant to Article 23 of Regulation (EC) No 998/2003 and took into account the recommendations made by EFSA.
- (18) On 11 December 2006, EFSA adopted an Opinion "Assessment of the risk of rabies introduction into the UK, Ireland, Sweden, Malta, as a consequence of abandoning the serological test measuring protective antibodies to rabies"¹⁰.
- (19) Based on 2005 data, EFSA identified that certain Member States have a non negligible prevalence of rabies in pet animals. In addition EFSA recommended that risk

⁹ http://ec.europa.eu/food/animal/liveanimals/pets/petreport_en.htm

¹⁰ The EFSA Journal (2006) 436, p. 1-54.

mitigating measures should be implemented with respect to the movement of pet animals from countries with non negligible prevalence in pet animals.

- (20) Rabies in those Member States is primarily of sylvatic nature. Field evidence demonstrated that with the elimination of sylvatic rabies as a result of intensive programmes of oral vaccination of wildlife, the disease occurrence in domestic animals diminishes.
- (21) The Community has approved a number of programmes for the eradication, control and monitoring of rabies in those Member States, pursuant to Article 24(5) of Council Decision 90/424/EEC on expenditure in the veterinary field¹¹. The Commission envisages ending EU support to national programmes in the territory of those Member States by the end of 2011.
- (22) In view of the EFSA Opinion and of the Community-supported programmes for the eradication of rabies in certain Member States, the transitional measure provided for in Article 6 of Regulation (EC) No 998/2003 should be extended until 31 December 2011.
- (23) On 18 January 2007, EFSA adopted an Opinion "Assessment of the risk of echinococcosis introduction into the UK, Ireland, Sweden, Malta and Finland as a consequence of abandoning the national rules"¹².
- (24) On 8 March 2007, EFSA adopted an Opinion "Assessment of the risk of tick introduction into the UK, Ireland, and Malta as a consequence of abandoning the national rules"¹³.
- (25) From those opinions, it results that the data available did not allow EFSA to demonstrate a particular status of the Member States applying the transitional measures with regard to certain ticks and the tapeworm *Echinococcus multilocularis* and to quantify the risk of pathogen introduction through the non-commercial movement of pet animals.
- (26) In order to ensure consistency as regards the transitional measures, it is appropriate to extend the transitional measure provided for in Article 16 until 31 December 2011.
- (27) Regulation (EC) No 998/2003 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 998/2003 is hereby amended as follows:

- (1) In Article 4(1), the second subparagraph shall be replaced by the following:

¹¹ OJ L 224, 18.8.1990, p. 19.

¹² The EFSA Journal (2006) 441, p. 1-54.

¹³ The EFSA Journal (2007) 469, p. 1-102.

'In the case referred to in point (b), where the transponder does not comply with the requirements set out in Annex Ia, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.'

(2) In Article 5(1), point (b) shall be replaced by the following:

'(b) be accompanied by a passport issued by a veterinarian authorised by the competent authority certifying that:

- (i) a valid anti-rabies vaccination was carried out on the animal in question pursuant to Annex Ib,
- (ii) where necessary, preventive measures regarding other diseases were carried out on the animal in question.'

(3) In Article 5(1), the following subparagraph shall be added:

'The preventive measures referred to in point (b)(ii) may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(4).'

(4) In the first subparagraph of Article 6(1), the introductory phrase and the first indent shall be replaced by the following:

'1. Until 31 December 2011, the entry of the pet animals listed in Part A of Annex I into the territory of Ireland, Malta, Sweden and the United Kingdom shall be subject to the following requirements:

- they must be identified in accordance with point (b) of the first subparagraph of Article 4(1), unless, until the end of the eight-year transitional period provided for in Article 4(1), the Member State of destination also recognises identification in accordance with point (a) of the first subparagraph of Article 4(1), and';

(5) Article 8(1) shall be amended as follows:

(a) In point (a), point (ii) shall be replaced by the following:

'(ii) until 31 December 2011, one of the Member States listed in part A of Annex II, either directly or after transit through one of the territories listed in part B of Annex II, satisfy the requirements of Article 6.'

(b) In point (b), point (ii) shall be replaced by the following:

'(ii) until 31 December 2011, one of the Member States listed in part A of Annex II, either immediately or after transit through one of the territories listed in part B of Annex II, be placed in quarantine.'

(6) In Article 14, the second paragraph shall be replaced by the following:

'In the case referred to in point (b) of the first subparagraph of Article 4(1), where the transponder does not comply with the requirements set out in Annex Ia, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.'

- (7) Article 16 shall be amended as follows:
- (a) in the first paragraph, the date '30 June 2010' shall be replaced by '31 December 2011';
 - (b) the second and third paragraphs shall be deleted.
- (8) Article 19 shall be replaced by the following:

Article 19

1. Part C of Annex I, Annex Ib and parts B and C of Annex II may be amended by the Commission to take account of developments in the situation within Community territory or in third countries as regards diseases affecting the species of animals covered by this Regulation, in particular rabies. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(4).

Annex Ia may be amended in accordance with the regulatory procedure referred to in Article 24(2) to take account of technological developments.

2. Where necessary, provisions may be laid down by the Commission, to specify the maximum number of pet animals which may be the subject of non-commercial movement, pursuant to this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(4).'

- (9) Two new Annexes, Annex Ia and Annex Ib, the texts of which are set out in the Annex to the present Regulation, shall be inserted.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

'ANNEX Ia

Technical requirements for the identification

For the purposes of Article 4(1), the standard electronic identification system shall be a read-only passive radio frequency identification device ('transponder'):

1. complying with standard ISO 11784 and applying HDX or FDX-B technology;
2. capable of being read by a reading device compatible with ISO 11785.

ANNEX Ib

Technical requirements for the anti-rabies vaccination (Referred to in Article 5(1)(b)(i))

For the purpose of Article 5(1) of Regulation (EC) No 998/2003, an anti-rabies vaccination shall be considered valid provided that the following requirements are complied with:

1. The anti-rabies vaccine must:
 - (a) be a vaccine other than a live modified vaccine and fall within one of the following categories:
 - (i) an inactivated vaccine of at least one antigenic unit per dose (WHO standard); or
 - (ii) a recombinant vaccine expressing the immunising glycoprotein of the rabies virus in a live virus vector;
 - (b) if administered in a Member State, have been granted a marketing authorisation in accordance with:
 - (i) Directive 2001/82/EEC, or
 - (ii) Regulation (EC) No 726/2004;
 - (c) if administered in a third country, meet at least the requirements laid down in Part C of Chapter 2.1.13 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008 Edition, of the World Organisation for Animal Health.
2. An anti-rabies vaccination may only be considered valid, if it meets the following conditions:
 - (a) the vaccine was administered on a date indicated in:
 - (i) Section IV of the passport; or
 - (ii) the appropriate section of the accompanying animal health certificate;
 - (b) the date referred to in point (a) must not precede the date of microchipping indicated in:
 - (i) Section III(2) of the passport; or
 - (ii) the appropriate section of the accompanying animal health certificate;
 - (c) at least 21 days must have elapsed since the completion of the vaccination protocol required by the manufacturer for the primary vaccination in accordance with the technical specification of the marketing authorisation referred to in point 1(b) for the anti-rabies vaccine in the Member State or third country in which the vaccination is administered;

- (d) the period of validity of the vaccination, as prescribed in the technical specification of the marketing authorisation for the anti-rabies vaccine in the Member State or third country where the vaccine is administered, must have been entered by the authorised veterinarian in:
 - (i) Section IV of the passport; or
 - (ii) the appropriate section of the accompanying animal health certificate;
- (e) a revaccination (booster) must be considered a primary vaccination if it was not carried out within the period of validity referred to in point (d) of a previous vaccination.'